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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
SOUAYA, JEHANNE E

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 07/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/786,011	SCHEU ET AL.	
	Examiner	Art Unit	
	Jehanne E Souaya	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *28 February 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Priority Documents

It is noted that a certified copy of the translation of application DE 19840044 was not found in the file.

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 9-13 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

3. Claims 1-7 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The recitation of "nucleic acid molecule" reads on a product of nature. This rejection can be overcome by the recitation of "an isolated nucleic acid molecule".

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with idiomatic errors. The claims should be rewritten to conform to claim language used in US practice. For instance, all claims lack an article at the beginning of the claims, such that the claims should recite "An isolated nucleic acid molecule...or "A kit".

B) Claims 1 and 3 are indefinite in step h because the recitation of "in each case" makes is unclear if step h encompasses the complements of each of a-g or any one of a-g. Further, the recitation of "complimentary" is unclear because it is unclear whether this term refers to the complete complement of any of SEQ ID NOS 1-7 or whether it refers to sequences that have some degree of complementarity to the recited SEQ ID NOS, but are not necessarily completely complementary to such.

C) Claim 2 is indefinite because the claim recites a number of different length limitations for the sequences such that it is unclear what the metes and bounds of the claim are unclear. Further, it is unclear what length limitation is encompassed by the recitation of "characterized by a length common for probes or primers" because probes can be thousands of nucleic acids long, as well as encompassing whole genes or parts of chromosomes, and PCR reactions have been taught in the art to be primed by whole genes. Accordingly, it cannot be determined what length limitations to the claimed nucleic acids are encompassed by the claims.

D) Claim 5 is indefinite in the recitation of "where appropriate" because it is unclear what is considered "appropriate" for modification. Neither the claim nor the specification make clear the metes and bounds of the claim.

E) Claim 6 is indefinite in the recitation of the phrase "building blocks known per se as probes and/or primers" as it is unclear how this claim further limits the invention. The term "building blocks" in relation to probes and primers is not an art recognized term and it cannot be determined from the claim language what limitations should be attributed to claim 6. In addition, the recitation of "per se" is not understood nor is it clear how this further limits the claim. It is further unclear how the nucleic acid molecule in claim 6 is "modified". Claim 6 is further unclear whether the recitation of "in particular" refers to the whole nucleic acid molecule or to any 10 successive nucleotides.

F) Claim 7 is indefinite in the recitation of "or additionally by" in line 3 as it is unclear how this is different from the modification or labeling step immediately preceding this recitation. Claim 7 is further indefinite in lines 6-10 as the language is confusing. The use of "in particular" renders the claim unclear as to what reactions are encompassed and what is being used to "aid". Further, the claim is unclear with respect to the recitation "nucleic acid-like" as it is unclear what characteristics the modified groups can possess such that they remain "nucleic-acid-like".

G) Claim 8 is indefinite because it is unclear if the kit for analytical detection purposes is a kit for detecting Listeria monocytogenes.

H) Claims 9-13 provide for the use of a set of nucleic acids, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is

intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Written Description

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to nucleic acid sequences with undefined upper length limitations (claims 1-2 and claims that depend from such) as well as sequences that contain differences with respect to the nucleotide composition of the nucleic acid molecule in relation to the recited SEQ ID NOS (claims 1-2, the use of the word "complimentary" for example, in claim 3; and all claims which depend from such). Particularly, claim 1 encompasses sequences that comprise a sequence that can have minimally 8, 9, or 10 successive sequences in common with any of SEQ ID NOS 1-7, sequences that are "complimentary" to SEQ ID NOS 1-7 (sequences that are "complimentary" to SEQ ID NO 1, for example, encompass sequences that are not necessarily completely complimentary to SEQ ID NO 1), or sequences that comprise a sequence that has a region with 90% homology to 10 successive nucleotides of any of SEQ ID NOS 1-7 (it is noted that the term "homology" is undefined and has been broadly interpreted to encompass sequences

with "similarity" and not necessarily "identity"). Claim 2 also encompasses all such recitations. Claim 3 encompasses sequences that are not necessarily completely complimentary to the recited SEQ ID NOS. Claims 4-13 are dependent from such claims. As such, the claims encompass whole genomes of different organisms that are not limited to Listeria or even specifically to Listeria monocytogenes due to the minimal amount of identity required between the recited SEQ ID NOS and the limitations of the claims. Further, the claims encompass mutants, variants, and homologs of the sequences recited from different species and strains of Listeria. The recitation of SEQ ID NOS 1-7, which are directed to sequences from a specific portion of Listeria monocytogenes genome are not representative of the genomic sequences from any organism or the mutants, variants, or homologous sequences from any species or strain of Listeria encompassed by the broadly claimed invention.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of sequences consisting of SEQ ID NOS: 1-7, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25

USPQ2d 1601, 1606 (CAFC 1993), and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-5, and 9-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Accession number Q20004, 1991, Geneseq database; which is taught in WO 91/18997; 1991.

Accession number Q20004 teaches a sequence of 63 base pairs, wherein from positions 41-51 it is identical to positions 1-11 of SEQ ID NO 6. Also, positions 37-51 of the accession number are identical to positions 5-19 of SEQ ID NO 7. With regard to claim 3, the claim is unclear with regard to what is encompassed by the term “complimentary”. Accession number

Q20004 contains a region from positions 22-33 which are completely complimentary to positions 6-20 of SEQ ID NO 7. With regard to claims 9-12, as the claims provide no positive steps, the disclosure of Q20004 that the sequence was used to bind to duplex target sequences is broadly interpreted to encompass the "use" claims 9-12.

9. Claims 1, 2, 6 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Matteucci et al; WO 91/18997; 1991.

Matteucci et al teach sequences (p. 18) which contain regions which have at least consecutive nucleotides in common with SEQ ID NO 7 (Ax-A on p. 18, from positions 9-16 is identical to positions 7-15 of SEQ ID NO 7). Further, Matteucci et al teach such sequence as Ax-B which contains a modified group at position 10, which meets the limitations of claims 6 and 7, "replaced by analogous building blocks… not naturally present in bacteria" and "modified groups of a nucleic acid-like structure" respectively.

10. Claims 1- 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Domann et al (Infection and Immunity, 1991, vol. 59, pp 65-72).

Domann et al teach a nucleic acid sequence (Fig 1) that anticipates the claimed nucleic acid sequences. It is noted that the claims are interpreted to encompass open language due to the fact that the claims were indefinite with respect to upper length limitations. Consequently, the full sequence of the mpl gene, as taught by Domann et al anticipate the claimed nucleic acid sequences. With regard to claim 3, Domann inherently teaches the complement of the sequence taught in figure 1, which is "complementary" to any of SEQ ID NOS 1-7.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 8 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matteucci et al; 1991; in view of Ahern, Holly (The Scientist; vol. 9, pp 1-5 from the internet; 1995).

Matteucci et al teach sequences (p. 18) which contain regions which have at least consecutive nucleotides in common with SEQ ID NO 7 (Ax-A on p. 18, from positions 9-16 is identical to positions 7-15 of SEQ ID NO 7). Matteucci et al do not teach these oligomers in kit format, however Ahern teaches that buying premade reagents and kits are convenient, therefore it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to provide the oligomers of Matteucci et al in kit format as taught by Ahern, the

improvement of providing the oligomers of Matteucci et al in a convenient format. The ordinary artisan would have been motivated to provide the oligomers of Matteucci et al in kit format because Ahern teaches that providing reagents necessary for analysis in kit format are convenient. It is noted that the use for the kits recited in the claims carries no patentable weight (with respect to claim 8). With respect to claim 13, as the "use" method sets forth no positive steps, nor recites how the kit is used, the use for the kit carries not patentable weight.

14. Claims 6-7 and 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Rossen et al (International Journal of Food Microbiology; 1991, vol. 14, pp 145-152) in view of Domann et al (Infection and Immunity, Jan 1991, vol. 59 p 65-72).

Rossen et al teach a PCR based method for specifically detecting Listeria monocytogenes in food samples (see abstract). Rossen et al teach constructing primers directed to a region upstream of the hemolysin gene which were successful in a method of specifically detecting L. monocytogenes (see Fig. 2, and p. 147). Rossen et al do not teach the nucleic acid sequence of this upstream region or the sequence of the primers LM14 or LM16, however, Domann et al teach a nucleic sequence which encodes a metalloprotease gene from listeria monocytogenes which is immediately upstream of the hemolysin gene. Domann et al teach the nucleotide sequence of this gene and also teach an alignment of the polypeptide encoded by the gene with other metalloprotease genes from other organisms (Figs 1 and 2) and teaches that this gene is unique to L. monocytogenes. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to construct primer sequences to detect L. monocytogenes as taught by Rossen for the purpose of detecting the harmful pathogen

in food samples. The ordinary artisan would have been motivated to do so because Rossen et al teaches the need for such assays. While Rossen et al do not teach specific sequences for such purposes, Rossen et al do teach a specific region within the Listeria genome that can be used to construct such sequences. As Domann et al teach that a gene specific for L. monocytogenes exists immediately upstream from the hemolysin gene, the ordinary artisan would have immediately recognized that such was the same region indicated by Rossen et al. It would have prima facie to one of ordinary skill in the art at the time the invention was made to construct primers and probes using the sequence of Domann et al for such purposes because the state of the art at the time of the invention was extremely high with regard to constructing probes and primers to known sequences for the purposes of identifying such sequences and because Rossen et al teach that primers to the region immediately upstream of the hemolysin gene were useful in a method of specifically detecting L. monocytogenes. Further, the teachings of Rossen et al provide the ordinary artisan with a reasonable expectation of success that primer sequences to the nucleic acid sequence taught by Domann et al would be capable of being used in a method of specifically detecting L. monocytogenes. Further, the teachings of Domann et al, that this sequence is unique to L. monocytogenes, would have provided further expectation of success that primers to such sequence could be constructed that would be capable of specifically detecting L. monocytogenes. It would have further been prima facie obvious to the ordinary artisan to modify such sequences to prevent degradation of the primers (claims 6 and 7). It is noted that the instantly pending claim are not directed to any particular sequences, but rather to sequences that can minimally encompass only 8 nucleotides of the recited SEQ ID NOS. Such sequences encompass a large genus of nucleic acids. Armed with the teachings of Rossen et al in

view of Domann et al, the ordinary artisan would have been motivated to construct a number of different primer sequences that would encompass the large genus of nucleic acids recited in the instantly pending claims.

15. Claims 8 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over unpatentable over Rossen et al in view of Domann et al, as applied to claims 3-7 and 9-12 above, and further in view of Ahern et al.

The teachings of Rossen et al in view of Domann et al are outlined above. Rossen et al in view of Domann et al do not teach primers in kit format, however, Ahern teaches that buying premade reagents and kits are convenient, therefore it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to provide the primers of Rossen et al in view of Domann et al, in kit format as taught by Ahern, for the improvement of providing the primers of Rossen et al in view of Domann et al in a convenient format. The ordinary artisan would have been motivated to provide the primers of Rossen et al in view of Domann et al in kit format because Ahern teaches that providing reagents necessary for analysis in kit format are convenient.

Conclusion

16. No claims are allowable over the cited prior art.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703) 308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya

Jehanne Souaya
Primary Examiner
Art Unit 1634

6/27/2003